UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

JEFFERY ALLEN FORTIN, Plaintiff, v. ABBOTT LABORATORIES, INC., AND ABBVIE, INC., Defendants.	NO. 2:24-CV-0279-TOR ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

BEFORE THE COURT is Defendants' Motion to Dismiss (ECF No. 9). This matter was submitted for consideration without oral argument. The Court has reviewed the record and files herein and is fully informed. For the reasons discussed below, Defendants' Motion to Dismiss (ECF No. 9) is GRANTED.

BACKGROUND

This matter arises out of alleged injury inflicted after Plaintiff received doses of the Humira vaccine in 2021. ECF No. 4 at 4. When he first began receiving Humira, he was told the side effects were "minimal," and included Tuberculosis

and "some infections." *Id*. Plaintiff maintains he received routine doses for ten months without incident. *Id*.

Plaintiff was also taking prednisone, a corticosteroid, to treat his rheumatoid arthritis and inflammation. *Id*. Defendants maintain that Humira's labeling contains a "black box" warning which states that patients treated with the drug "are at increased risk for developing serious infections that may lead to hospitalization or death," and "[m]ost patients who developed these infections were taking concomitant immunosuppressants such as . . . corticosteroids." ECF No. 9 at 3. Then, on or about October 6, 2021, Plaintiff noticed that his vision became blurry and obstructed by floaters, in response to a stressful event. ECF No. 4 at 5. Plaintiff went to his rheumatologist, who referred him to a specialist that recommended surgery to repair damage to his eye. *Id*. Plaintiff ultimately declined the surgery because he was advised that the risk outweighed the reward. *Id*.

Plaintiff presents that he has been diagnosed with ocular disease, ocular retinitis of the right eye, and developed chickenpox in his right eye. *Id*. at 7. To treat the infection, Plaintiff had to receive three shots in his right eye and has permanent vision loss. *Id*. Also, as a result of this sudden vision loss, Plaintiff states that he fell getting out of bed and broke his wrist. *Id*. He alleges he will be required to take immune system support drugs for the rest of his life. Plaintiff

attributes his vision loss and related impairments to receiving Humira because his "T-cell count," increased after he stopped receiving the drug. *Id*.

Defendants move for dismissal under Federal Rule of Civil Procedure 12(b)(6), arguing that Plaintiff has failed to establish any cognizable claim under the Washington Product Liability Act, and has likewise failed to respond in substance to the motion. ECF Nos. 9, 13. Plaintiff has filed a "Motion to Quash," and for leave to file a Second Amended Complaint. ECF No. 12.

DISCUSSION

I. Motion to Dismiss Standard

Federal Rule of Civil Procedure 12(b)(6) provides that a defendant may move to dismiss the complaint for "failure to state a claim upon which relief can be granted." A 12(b)(6) motion will be denied if the plaintiff alleges "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A motion to dismiss for failure to state a claim "tests the legal sufficiency" of the plaintiff's claims. *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). While the plaintiff's "allegations of material fact are taken as true and construed in the light most favorable to the plaintiff" the plaintiff cannot rely on "conclusory allegations of law and unwarranted inferences ... to defeat a motion to dismiss for failure to state a claim." *In re Stac Elecs. Sec. Litig*.,

89 F.3d 1399, 1403 (9th Cir. 1996) (citation and brackets omitted). That is, the plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements." *Twombly*, 550 U.S. at 555. Instead, a plaintiff must show "factual content that allows the court to draw the reasonable inference that the defendant is liable for the alleged misconduct." *Iqbal*, 556 U.S. 662. A claim may be dismissed only if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Navarro*, 250 F.3d at 732.

Here, Plaintiff is proceeding pro se. While pro se pleadings are held to less stringent standards than those prepared by attorneys, pro se litigants in the ordinary civil case should not be treated more favorably than parties with attorneys of record. *See Jacobsen v. Filler*, 790 F.2d 1362, 1364 (9th Cir. 1986).

Federal Rule of Civil Procedure 15 provides that "the court should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). In deciding whether leave to amend should be granted, a court must consider the following five factors: "(1) bad faith; (2) undue delay; (3) prejudice to the opposing party; (4) futility of amendment; and (5) whether the plaintiff has previously amended his complaint." *Nunes v. Ashcroft*, 375 F.3d 805, 808 (9th Cir. 2004). The Ninth Circuit has repeatedly instructed district courts to "grant leave to amend even if no request to amend the pleading was made, unless . . . the

pleading could not possibly be cured by the allegation of other facts." *Lopez v. Smith,* 203 F.3d 1122, 1130 (9th Cir.2000).

As a preliminary matter, the Court considers Defendants' Motion to Dismiss as it relates to Plaintiff's First Amended Complaint. ECF No. 4. Pursuant to Federal Rule of Civil Procedure 15(a)(1)(A), a party may amend its pleading once as a matter of course, provided it does so within 21 days of filing the complaint, or, if the pleading is one which requires a response, within 21-days of the filing of defendant's answer. Fed. R. Civ. P. 15(a)(1)(B). Outside of that window, a party may only amend its complaint with the opposing party's written consent or a grant of leave from the court. Fed. R. Civ. P. 15(a)(2). The Court construes Plaintiff's filings at ECF Nos. 12 and 14 in part as a Response to Defendants' Motion to Dismiss, and in part as a Motion to Amend. But because Plaintiff has not yet satisfied Federal Rule of Civil Procedure 15(a)(2), the Court considers the arguments of all parties only as they relate to the operative Complaint found at ECF No. 4.

II. The Washington Products Liability Act

This matter is before this Court on the basis of its diversity jurisdiction pursuant to 28 U.S.C. § 1332(a)(1); Plaintiff is a citizen of Washington State and Defendants are citizens of Delaware and Illinois. And the amount in controversy

exceeds $75,000. ECF Nos. 4, 10, 11. As a federal court sitting in diversity jurisdiction in Washington, this Court applies Washington's choice-of-law rules. *See Patton v. Cox*, 276 F.3d 493, 495 (9th Cir. 2001). Washington courts will only engage in a choice-of-law analysis if there is actual conflict between Washington law and the laws or interests of another state. *FutureSelect Portfolio Mgmt., Inc. Tremont Grp. Holdings, Inc*., 180 Wash. 2d 954, 967 (2014). Here, both parties are seemingly in agreement that Washington law applies.

This claim is properly analyzed under the Washington Product Liability Act ("WPLA"), the exclusive remedy for product liability claims under Washington law. *See Bylsma v. Burger King Corp*., 176 Wash. 2d 555, 559 (2013). To successfully state a claim for relief under the WPLA, a plaintiff must demonstrate that his or her injury was proximately caused by the negligence of the manufacturer through four general categories: (1) defective design; (2) a failure to warn; (3) defective manufacturing; or (4) a breach of express or implied warranty. RCW 7.72.030. Plaintiff's First Amended Complaint does not provide discrete causes of action under Washington law. While a plaintiff need not define these specific theories of liability prior to conducting discovery, in order to survive a motion to dismiss, the complaint must contain sufficient non-conclusory factual allegations to support at least one of the factors available under the WPLA. *Staub v. Zimmer, Inc*., No. C17-0508JLR, 2017 WL 2506166, at *2 (W.D. Wash. June 9,

2017).

1. Defective Design

Plaintiff's First Amended Complaint does not contain any claim related to design defect, but his response to Defendants' Motion to Dismiss lays out two separate theories. First, he argues that Humira's design is not reasonably safe because consumers would not expect the level of immune suppression and resulting infection he has experienced. ECF No. 14 at 8. Next, he argues that the existence of other drugs with "more targeted mechanisms of action," proves that Humira could be produced more safely in a technically and economically feasible way. *Id*. at 9.

To successfully claim defective design, a plaintiff's complaint must contain allegations that "at the time of manufacture, the likelihood that the product would cause plaintiff's harm or similar harms, and the seriousness of those harms outweighs the burden on the manufacturer to design a product that would have prevented those harms and the adverse effect" and that a practical, feasible alternative design would not have an adverse effect on the product's usefulness. RCW § 7.72.030(1)(a).

However, claims of design defects of pharmaceutical drugs are preempted by federal law when they conflict with a state law risk balancing test. See U.S. CONST., Art. VI, cl. 2; *Gade v. National Solid Wastes Management Assn*., 505 U.S.

88, 108 (1992). Even without an expression of preemption within a federal law, a state law is still preempted when it is "impossible for a private party to comply with both state and federal requirements." *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990).

The Federal Food, Drug, and Cosmetic Act ("FDCA") mandates that the Food and Drug Administration ("FDA") approve any name brand or generic drug before a manufacturer may market it in interstate commerce. 21 U.S.C. § 355. "Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013) (citing 21 C.F.R. § 314.70(b)(2)(i)); *see also Holcomb v. Pfizer, Inc.*, No. 120CV01008ADABAM, 2022 WL 17670003, at *5 (E.D. Cal. Dec. 14, 2022) ("Even when a plaintiff identifies a specific defect, however, federal regulations make it impossible for manufacturers to make 'major changes' to a prescription drug in response to a state law risk/benefit balancing test without pre-approval from the FDA."). Thus, to the extent that Plaintiff is lodging a claim that Defendants could have made the product safer at any point after it was approved by the FDA, such claim is preempted.

Construed liberally, Plaintiff seems to be advancing an argument that

Defendants could have developed a safer product prior to FDA approval. While not contained in the First Amended Complaint itself, he argues in his Response, "plaintiff's design defect claim centers not on unapproved changes to Humira's formulation but rather on the product's overall safety and whether alternative designs could have reduced harm." ECF No. 14 at 10.

Preemption aside, it does not appear that Humira is defective in design. In his Motion to Quash, Plaintiff points to two tests Washington state courts have operationalized to determine whether a product is defectively designed: the risk utility test and the consumer expectations test. *Thongchoom v. Graco Children's Prods., Inc.*, 117 Wash. App. 299, 304 (2003). The risk utility test questions the likelihood that the manufactured product would have caused a plaintiff's harms, and whether the manufactured had a duty to design a product that would have prevented those harms given their seriousness. *Soproni v. Polygon Apartment Partners*, 137 Wash. 2d 319, 326 (1999). Washington courts have looked to whether a different design would be feasible while keeping in mind the product's purpose. *See Thongchoom*, 117 Wash. App. at 304 (finding that a change in design to a product designed to give a baby mobility would render the product useless for its intended purpose); *Neilson v. Corp. of Presiding Bishop of Church of Jesus Christ of Latter Day Saints*, 113 Wash. App. 1050 (2002) (holding that a change in design to a trampoline would not have prevented injury). Under the consumer

expectation test, a plaintiff must show "[t]he relative cost of the product, the gravity of the potential harm from the claimed defect and the cost and feasibility of eliminating or minimizing the risk." *Pagnotta v. Beall Trailers of Oregon, Inc.,* 99 Wash.App. 28, 36 (2000) (quoting *Seattle–First Nat'l Bank v. Tabert*, 86 Wash.2d 145, 154 (1975)). Under the consumer expectation test, a manufacturer may not be held liable just because a product causes harm, it must be demonstrated that the product is not reasonably safe. *Neilson*, 113 Wash. App. 1050 (2002).

Plaintiff's risk utility theory is essentially that because other drugs with different formulations function similarly to Humira, it is feasible to design the drug in a safer way. In addition to being vague, what is lacking from this line of reasoning is a consideration of how Humira and drugs like it work. Plaintiff does not put forward an allegation that he could take another drug that treats rheumatoid arthritis in conjunction with a corticosteroid and not be exposed to the same level of risk for immune suppression. And given the purpose of rheumatoid arthritis treatments like Humira, to interact with the immune system to reduce inflammation, it doesn't seem likely that he could make such an argument. ECF Nos. 9 at 3 ("Plaintiff alleges that his rheumatologist prescribed him Humira for treatment of his rheumatoid arthritis and inflammation.") and 13 at 8 ("Humira is described in its own labeling as an immunosuppressant.")

Plaintiff's consumer expectation argument fairs no better. Plaintiff argues

that there is no way that a consumer, even under the supervision of a doctor, could possibly know about the risk of immune suppression when taking Humira. The first line of the warning label states[1]:

> Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

ECF No. 9 at 3.[2]

Within the first page of the warning label, the document discusses patients

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[1] The Court may take judicial notice of Humira's FDA approved warning label without converting a Rule 12(b)(6) Motion to Dismiss into a Rule 56 Motion for Summary Judgment. Pursuant to Federal Rule of Evidence 201(b), "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot be reasonably questioned." Here, the FDA's warning label falls into the latter category, a "source whose accuracy cannot be reasonably questioned." *See Curtis v. Inslee,* 709 F. Supp. 3d 1257, 1265 (W.D. Wash. 2023).

[2] Citing to FDA Labeling, https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125057s418s419lbl.pdf (last visited December 16, 2024)

increased risk for bacterial, viral, and other infections, and cautions that the risks and benefits of the treatment should be weighed before beginning treatment in patients with chronic or recurrent infections. The warning box directs the administer of Humira to Subsection 5, where it details that certain side effects, including serious infections due to viral pathogens, have been discovered in patients, especially those taking an immunosuppressant such as a corticosteroid.[3] The label also discusses that some people who have experienced such infections have been hospitalized or died.[4] And it cautions against prescribing Humira for patients taking an immunosuppressant because those patients will be a greater risk for an opportunistic infection. Plaintiff argues that the specific risks of a resurgence of chickenpox, ocular side effects, and intense immune suppression were not explicitly mentioned within the warning label, and thus a patient receiving the drug could not have anticipated the degree of side effects. ECF No. 14 at 9. With respect to the intense immune suppression, the Court disagrees, finding that the label is rife with warnings that Humira increases the risk of immune suppression when taken with a corticosteroid, which could lead to a viral infection, like a resurgence of chickenpox. Thus, patients who received Humira

[3] *Id.*

[4] *Id.*

while taking a corticosteroid should be on notice of the risk of intense immune suppression that may lead to a viral infection.

Plaintiff's claim for design defect does not appear in his First Amended Complaint, and the Court dismisses this cause of action with prejudice because, based on the above reasoning, amendment would be futile. *See United States v. Corinthian Colleges*, 655 F.3d 984, 995 (9th Cir.2011).

2. Duty to Warn

Plaintiff's First Amended Complaint alleges that he was not adequately warned of the possible side effects of Humira when he first began taking it in January of 2021. ECF No. 4 at 4. In taking into account his Response to Defendants' Motion to Dismiss, he seems to also advance a theory that his doctor was not made aware of the risks involved in administering Humira, including the possibility that a patient may suffer with ocular chickenpox as a result of a suppressed immune system. ECF No. 14 at 7. His argument centers on the idea that if he had been aware of the risks, he would not have pursued Humira in the course of his treatment.

In general, a plaintiff must show that (1) a manufacturer's product (2) was not reasonably safe because of lack of adequate warnings or instructions, which (3) caused him or her harm. *O'Connell v. MacNeil Wash Sys. Ltd.*, 2 Wash. App. 2d 238, 246 (2017). But in relation to prescription drugs, Washington deploys the

"learned intermediary doctrine," whereby the manufacturer may satisfy its duty to warn the patient if it properly warned the prescribing physician of the risks of the product. *Taylor v. Intuitive Surgical, Inc*., 187 Wash.2d 743, 757 (2017) (citing *Terhune v. A.H. Robins Co.,* 90 Wash.2d 9, 14 (1978)); *see also Dearinger v. Eli Lilly & Co*., 199 Wash. 2d 569, 575–77 (2022). The learned intermediary doctrine rests on the principle that a doctor is in a better position to communicate warnings from the manufacturer to their patient. *Id*. Here, Plaintiff's bare assertion that his rheumatologist was not properly warned of the potential risks associated with prescribing Humira to a patient taking a corticosteroid does nothing to rebut Defendants' contention that a disclaimer detailing both the immunosuppressant qualities of Humira and the risk of viral infection was provided with the drug.[5] ECF No. 9 at 3.

The Court will likewise not allow for amendment based on Plaintiff's cause of action for failure to warn based on futility. *Corinthian Colleges*, 655 F.3d at 995.

3. Defective Manufacturing

In order to successfully plead a claim for a defect in manufacturing, a

[5] See FDA Labeling, https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125057s418s419lbl.pdf (last visited December 16, 2024).

plaintiff must demonstrate that when a product left the control of the manufacturer the product deviated in some material way from the design specifications or performance standards of the manufacturer, or deviated in some material way from otherwise identical units of the same product line, or from ostensibly identical units of the same product line. RCW 7.72.030(2)(a). A defective manufacturing claim also requires a plaintiff to allege that the manufacturing defect is the proximate cause of plaintiff's injuries. RCW § 7.72.030(1); *Hernandez v. Johnson & Johnson*, No. 4:20-CV-05136-SMJ, 2021 WL 320612, at *4 (E.D. Wash. Jan. 8, 2021).

Here, Plaintiff's First Amended Complaint does not mention any allegation of defective manufacturing whatsoever. In his Response, Plaintiff argues that his suppressed immune system is evidence that some number of doses of Humira he received, "deviated materially from its intended design and specifications, resulting in severe and unexpected health complications." ECF No. 14 at 11. Plaintiff presents that the resulting infections he experienced provide support that Humira's production suffers from dangerous inconsistencies and argues he should be entitled to prove these allegations through discovery. *Id*. at 12. However, given the express warning that Humira may result in levels of immune suppression that have resulted in hospitalization or death, the Court does not find that an allegation that some number of doses that Plaintiff received between January 2021 and October

2021 deviated from that express warning. This claim is likewise dismissed without leave to amend for futility.

4. Breach of Expressed or Implied Warranties

Once again, the operative Complaint contains no allegation of a breach of either an expressed or implied warranty. Plaintiff argues Defendants made promises that Humira was safe and effective, both through product information and communication with healthcare providers, as well as implicitly through a reasonable expectation that the product was safe for its intended purposes. ECF No. 14 at 14–15. Under the WPLA, a plaintiff may show a breach of express warranty by demonstrating (1) the warranty was part of the basis of the bargain; (2) the warranty relates to a material fact; and (3) the warranty turns out to be untrue. Wash. Rev. Code § 7.72.030(2)(b). Usually, the plaintiff must be in contractual privity with the seller. *Stepp v. Takeuchi Mfg. Co*. (U.S.) Ltd., No. C07-5446RJB, 2008 WL 4460268, *10 (W.D. Wash. Oct. 2, 2008). Even in his Response, Plaintiff does not point to a specific place where Defendants have marketed or provided information to prescribing physicians detailing that Humira is safe and effective for use in every situation. *See Iqbal*, 556 U.S. at 663 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."). He does not rebut the contention that Defendants provided a disclaimer about the immune systems effects of mixing the drug with a

corticosteroid as part of the warning label, meaning it was explicitly not held out as safe for use while receiving certain other types of medication. And while he mentions privity, Plaintiff does not demonstrate that he and Defendants were in privity of contract giving rise to a duty. ECF No. 14 at 15.

To state a claim for breach of an implied warranty under Title 62A RCW, the Washington State Uniform Commercial Code, a plaintiff must be in privity with the defendant. *Baughn v. Honda Motor Co*., 107 Wash. 2d 127, 151 (1986). To reiterate, Plaintiff does not actually allege in his First Amended Complaint or in the Response that he is in privity with Defendants. Moreover, Plaintiff must identify the specifics of a breached implied warranty. *Armstrong v. Atrium Med. Corp*., No. 1:22-CV-03007-MKD, 2022 WL 17258345, at *4 (E.D. Wash. Nov. 10, 2022). Under the implied warranty of merchantability, goods are merchantable if they are "fit for the ordinary purposes for which such goods are used." RCW 62A.2–314(2)(c). Here, Plaintiff provides "the implied warranty of merchantability guarantees that Humira would be fit for its ordinary purpose as an immunomodulatory medication," and because of the severity of his immune system suppression, the drug failed to meet safety and effectiveness standards. ECF No. 14 at 14, 15. Besides this being the kind of conclusory statement reciting the elements of the statute not permitted in *Twombly*, 550 U.S. at 555, Plaintiff does not provide support for his breach of a warranty of merchantability claim

because Humira is designed to suppress the user's immune system. As such, this cause of action is also dismissed without leave to amend. *Corinthian Colleges*, 655 F.3d at 995.

ACCORDINGLY, IT IS HEREBY ORDERED:

1. Defendants' Motion to Dismiss (ECF No. 9) is **GRANTED**.
2. Plaintiff's First Amended Complaint (ECF No. 4) is **DISMISSED with prejudice**.

The District Court Executive is directed to enter this Order and Judgment accordingly, furnish copies to parties, and **CLOSE** the file.

DATED December 17, 2024.

THOMAS O. RICE
United States District Judge